The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT JOHN MACLEOD WILSON,
CONRAD WILLIAM MULLINEAUX
and ANNA ELIZABETH LAW

Appeal No. 2004-0472
Application No. 09/787,633

REMAND TO EXAMINER

Before ELLIS, MILLS, and GREEN, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

REMAND TO THE EXAMINER

The above-identified application is being remanded to the examiner for appropriate action. The appellants filed a Reply Brief, dated August 18, 2003; however, it is not apparent from the record whether it has been entered and considered by the examiner.

We have not yet considered the merits of the examiner's position. Nevertheless, we point out that upon return of the application, the examiner might wish to consider the following in addition to the current rejection pursuant to 35 U.S.C. § 112, first paragraph.

1. We note that claims 12 and 13, the only claims pending in the application, are directed to the use of any "test compound" which inhibits the activity of, or binds to, the ycf 24 gene product in a manner which may suggest the inhibition of the growth of the organism. Upon return of the application, the examiner may wish to consider whether the claims are vague and indefinite in the recitation of a "test compound." Specifically, what type of compounds do the appellants intend? See, 35 U.S.C. § 112, second paragraph.

We point out that the analysis of whether the claims "set out and circumscribe a particular area with a reasonable degree of precision and particularity" involves reading the claims "in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971)("It is important here to understand that under this analysis claims which on first reading--in a vacuum, if you will-- appear indefinite may upon a reading of the specification disclosure or prior art teachings become quite definite. It may be less obvious that this rule also applies in the reverse, making an otherwise definite claim take on an

unreasonable degree of uncertainty"). We further point out that the specification does not provide a single working example of a "test compound" which is capable of inhibiting, or binding to, a ycf 24 gene product. We still further point out that the specification states that the cellular location of the ycf 24 product is not known. Specification, p. 6, line 30- p. 7, line 3. Thus, the examiner may wish to consider whether upon reading the specification, it is clear which substances are even candidates for being a "test compound." Antisense compounds? Antibodies? Pharmaceutical compositions?

2. In addition, the examiner may wish to consider whether the specification provides an adequate written description and/or would have enabled one skilled in the art to make and use the claimed "test compounds." For example, to the extent that the appellants may intend that the claims are directed antisense test compounds we point out that the specification simply states that an antisense polynucleotide may hybridize to all or part of the ycf 24 mRNA. Specification, p. 12, lines 23-24; see also, p. 13, lines 6-18. However, the specification does not disclose a single example of an antisense polynucleotide having the claimed characteristics. To the contrary, the specification concludes that work is in progress to determine the nature of the nucleotide "sequence required for cellular localization which might be susceptible to disruption by an antisense approach." Id., p. 26, lines, 7-12. Thus, the examiner might wish to consider whether the specification provides an adequate written description and/or an enabling

disclosure of the nucleotide sequences (i) within the ycf 24 gene, which are viable targets for antisense inhibition of organism growth; and (ii) of any antisense test compounds having the claimed characteristics. See, e.g., University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 reh'g denied (en banc) cert. denied, 523 U.S. 1089 (1998).

We point out that the claims are not limited to antisense test compounds. Thus, in reviewing the specification, and the numerous suggestions therein as to possible "test compound" candidates, the examiner may wish to consider the factors set forth by the court in In re Wands, 858 F.2d 731, 736, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), and make a determination on the record as to whether (i) the specification would have enabled one skilled in the art to make and use the claimed invention; or (ii) the appellants simply "tossing out the mere germ of an idea?" Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997)("Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable").

3. Finally, we note that claim 13 is directed to a method wherein the organism is a malaria parasite. The specification discloses the nucleotide sequence of the ycf 24

gene of only one type of human malaria, Plasmodium falciparum. We point out that there are four types of human malaria, as well as several primate and rodent malarias. We further point out that the malaria parasite has a complex life cycle which involves two distinct stages, the sporozoite stage which develops in a mosquito, and the merozoite stage which develops in red blood cells. However, the specification does not disclose when during the parasite life cycle the ycf 24 gene is expressed. We still further point out that after being injected by the mosquito, the sporozoite stage is only present in the human blood stream for 15-20 minutes before entering the liver. The merozoite stage is present in the blood stream for an even shorter period of time (after the infected blood cell is lysed and until a new blood cell is infected). Thus, given that the claims read on in vivo inhibition of parasite growth, the lack of any teachings in the specification as to the stage in the malarial parasite's life cycle in which the ycf 24 gene is expressed, and the brief period of time said parasite is available for contact with any "test compound," regardless of the life cycle stage in which the gene is expressed, the examiner may wish to consider whether the teachings of the specification would have enabled on skilled in the art to make and use the invention described in claim 13. Genentech Inc. v. Novo Nordisk A/S, 108 F.3d at 1366, 42 USPQ2d at 1005("Tossing

out the mere germ of an idea does not constitute enabling disclosure"); In re Wands, 858 F.2d at 731, 8 USPQ2d at 1404.

REMAND

JOAN ELLIS
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

JE/dpv

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